

IN THE CLAIMS

1. (currently amended): A pharmaceutical dosage form of a combination of a high dose high solubility active ingredient, in the form of a modified release formulation and a low dose active ingredient selected from the group comprising of glibenclamide (glyburide), glipizide, gliclazide, glimepiride, tolazamide, tolbutamide, chlorpropamide, gliquidone, nateglinide, mitiglinide, glyburide, glisoxepid, glibornuride, phenbutamide, tolcyclamide, repaglinide, troglitazone, ciglitazone, rosiglitazone, pioglitazone, englitazone, acarbose, voglibose, emiglitate, miglitol, farqlitazar, (S)-2-ethoxy-3-[4-(2-(4-methanesulfonyloxyphenyl)ethoxy)phenyl]propanoic acid, 3-(4-[2-4-tert-butoxycarbonylaminophenyl)ethoxy]phenyl)-(S)-2-ethoxy propanoic acid and pharmaceutically acceptable salts thereof as an immediate release formulation suitable for swallowing; ~~which comprises~~ said dosage formulation comprising an inner portion having [(a)] the low dose active ingredient as an immediate release formulation and an outer portion having [(a)] the high dose, high solubility active ingredient as modified release, wherein said inner portion is covered by the outer portion from all the sides except a top surface that remains uncovered; wherein said outer portion is prepared by using dual retard technique to control the release of the high dose high solubility activity active ingredient, wherein the said dual retard technique is a combination of a matrix formulation and a reservoir formulation and comprises

a) micro matrix particles consisting of a high dose, high solubility active ingredient and one or more hydrophobic release controlling agents wherein the weight ratio of high dose, high solubility active ingredient and hydrophobic release controlling agent is in the range of 100:2.5 to 100:30 and said high dose, high solubility active ingredient is selected from the group consisting of metformin hydrochloride, phenformin and buformin and the low dose active ingredient is an antidiabetic drug selected from the group comprising of glibenclamide (glyburide), glipizide, glimepiride, tolazamide, tolbutamide, chlorpropamide, glimepiride, nateglinide, mitiglinide, glyburide, glisoxepid, glibornuride, phenbutamide, tolazamide, repaglinide, troglitazone, ciglitazone, rosiglitazone, pioglitazone, englitazone, acarbose, voglibose, emiglitazone, miglitol, farglitazax, (S)-2-ethoxy-3-(4-(2-(4-methanesulfonyloxyphenyl)ethoxy)-phenyl)propanoic acid, 3-(4-(2-(4-tert-butoxycarbonylaminophenyl)ethoxy)phenyl)-(S)-2-ethoxypropanoic acid and pharmaceutically acceptable salts thereof and the high dose high solubility active ingredient is an antidiabetic drug selected from the group consisting of metformin hydrochloride, phenformin and buformin,

b) a coating of one or more hydrophobic release controlling agents on said micro matrix particles, wherein the weight ratio of micromatrix particles and hydrophobic release controlling agent is in the range of 100:2.5 to 100:30.

2-4. (canceled)

5. (currently amended) A dosage form according to claim 1, wherein the hydrophobic release controlling agents are selected from the group ~~comprising~~ consisting of poly(ethyl acrylate, methyl methacrylate, trimethylammonioethyl methacrylate chloride) 1:2:0.1; poly(ethyl acrylate, methyl methacrylate, trimethylammonioethyl methacrylate chloride) 1:2:0.2 and poly(ethylacrylate, methyl methacrylate) 2:1 ammonio methacrylate copolymers type A and B as described in USP, methacrylic acid copolymer type A, B and C as described in USP, polyacrylate dispersion 30% as described in Ph. Eur., polyvinyl acetate dispersion, ethylcellulose, cellulose acetate, cellulose propionate (lower, medium or higher molecular weight), cellulose acetate propionate, cellulose acetate butyrate, cellulose acetate phthalate, cellulose triacetate, poly(methyl methacrylate), poly(ethyl methacrylate), poly(butyl methacrylate), poly(isobutyl methacrylate), poly (hexyl methacrylate), poly(isodecyl methacrylate), poly (lauryl methacrylate), poly(phenyl methacrylate), poly (methyl acrylate), poly (isopropyl acrylate), poly (isobutyl actylate), poly (octadecyl acrylate), waxes selected from the group consisting of beeswax, carnauba wax, microcrystalline wax, and ozokerite; fatty alcohols selected from the group consisting of cetostearyl alcohol, stearyl alcohol; cetyl alcohol and myristyl alcohol; and fatty acid esters selected from the group consisting of glyceryl monostearate, glycerol distearate, glycerol monooleate, acetylated monoglycerides, tristearin, tripalmitin, cetyl esters wax, glyceryl palmitostearate, glyceryl behenate and hydrogenated castor oil.

6. (previously presented) A dosage form according to claim 5, wherein the hydrophobic release controlling agent(s) is selected from the group consisting of ammonio methacrylate co-polymers.

7. (currently amended) A dosage form according to claim 6, wherein the ammonio methacrylate co-polymers are selected from the group consisting of poly(ethyl acrylate, methyl methacrylate, trimethylammonioethyl methacrylate chloride) 1:2:0.1; poly(ethyl acrylate, methyl methacrylate, trimethylammonioethyl methacrylate chloride) 1:2:0.2 and poly(ethyl acrylate, methyl methacrylate) [[1]] 2:1

8-10. (canceled)

11. (currently amended) A dosage form according to claim 1, wherein in micro matrix particles, the active ingredient and one or more hydrophobic release controlling agents are present in a weight ratio of from 100:2.5 to 100:[[20]] 30.

12. (currently amended) A dosage form according to claim 1, wherein said coating on said micro matrix particles ~~comprises~~ consists of one or more hydrophobic release controlling agents.

13. (canceled)

14. (previously presented) A dosage form according to claim 1, wherein the hydrophobic release controlling agent(s) is selected from fatty acid esters.

15. (currently amended) A dosage form according to claim 14, wherein the hydrophobic release controlling agents is selected from the group ~~comprising~~ consisting of hydrogenated castor oil and glycerol distearate.

16-17. (canceled)

18. (currently amended) A dosage form according to claim 1, wherein in outer portion, micro matrix particles and coating of one or more hydrophobic release controlling agents are present in a weight ratio of from 100:2.5 to 100:[[20]] 30.

19. (original) A dosage form according to claim 1, wherein the weight ratio of immediate release active ingredient and modified release active ingredient is from 1:10 to 1:15000.

20. (Currently Amended) A dosage form according to claim 1, wherein the low dose active ingredient consist of dose less than or equal to 50 mg.

21-22. (canceled)

23. (currently amended) A dosage form according to claim 1, wherein the high dose, high solubility active ingredient ~~comprises~~ consists of a dose from 500 mg to 1500 mg.

24-29. (canceled)

30. (withdrawn) A process for the preparation of a dosage form as claimed in claim 1, comprising a) preparation of inner portion and b) preparation of outer portion.

31. (withdrawn) A process for the preparation of a dosage form as claimed in claim 30, wherein preparation of outer portion comprising a) preparing a micro matrix particles containing high dose, high solubility active ingredient and one or more hydrophobic release controlling agent and b) coating the said micro matrix particles containing high solubility active ingredient and one or more hydrophobic release controlling agent.

32-51. (canceled)

52. (currently amended) A dosage form according to claim 1, wherein the low dose antidiabetic active ingredient ~~comprises~~ consist of a dose less than or equal to 50 mg.

53-56 (canceled)

57. (currently amended) A dosage form according to claim 1, wherein the high dose high solubility antidiabetic active ingredient ~~comprises~~ consists of a dose from 500 mg to 1500 mg.

58. (previously presented) A dosage form according to claim 1, which is a once a day oral formulation.

59. (canceled)

60. (previously presented) A dosage form according to claim 1, wherein the high dose high solubility antidiabetic active ingredient is metformin hydrochloride.

61. (currently amended) A dosage form according to claim 60, wherein the composition of outer portion is as follows-

Micro matrix particles-

Metformin hydrochloride 75%w/w to 99%w/w

~~Eudragit-RC~~ poly(ethylacrylate, methyl methacrylate, trimethylammonioethyl methacrylate chloride 1:2:0.1 1%w/w to 25%w/w

Coated micro matrix particles

Micro matrix particles 70%w/w to 99%w/w

Hydrogenated castor oil 1%w/w to 30%w/w

Magnesium stearate 0%w/w to 2%w/w

62-67 (canceled)

68. (currently amended) A dosage form according to claim [[33]] 1, wherein the low dose antidiabetic active ingredient is rosiglitazone maleate.

69. (previously presented) A dosage form according to claim 1, wherein the low dose antidiabetic active ingredient is glimepiride.

70. (canceled)

71. (previously presented) A dosage form according to claim 1, wherein inner portion may optionally contain more than one antidiabetic active ingredients.

72. (canceled)

73. (withdrawn) A process for the preparation of a dosage form as claimed in claim 33, comprising a) preparation of inner portion and b) preparation of outer portion.

74. (withdrawn) A process for the preparation of a dosage form as claimed in claim 73, wherein preparation of outer portion comprising a) preparing a micro matrix particles containing high dose, antidiabetic active ingredient and one or more hydrophobic release controlling agent and b) coating the said micro matrix particles containing high dose antidiabetic active ingredient and one or more hydrophobic release controlling agent.

7[[3]]5. (currently amended) A pharmaceutical dosage form of a combination of a high dose high solubility active ingredient, in the form of a ~~as~~ modified release formulation and a low dose active ingredient is an antidiabetic drug selected from the group consisting of glibenclamide (glyburide), glipizide, gliclazide, glimepiride, tolazamide, tolbutamide, clorpropamide, gliquidone, nateglinide, mitiglinide, glyburide, glisoxepid, glibornuride, phenbutamide, tolcyclamide, repaglinide, troglitazone, ciglitazone, rosiglitazone, pioglitazone, englitazone, acarbose, voglibose, emiglitate, miglitol, farglitazar, (S)-2-ethoxy-3-[4-(2-[4-methanesulfonyloxyphenyl]ethoxy)phenyl]propanoic acid, 3-[4-[2-4-tert-butoxycarbonyl aminophenyl]ethoxy]phenyl)-(S)-2-ethoxy propanoic acid and pharmaceutically acceptable salts thereof as an immediate release formulation suitable for swallowing; which comprises an inner portion having a low dose active ingredient as immediate release and an outer portion having a high dose, high solubility active ingredient as modified release, wherein said inner portion is covered by the outer portion from all the sides except a top surface that remains uncovered; wherein said outer portion consists of:

a) micro matrix particles consisting of a high dose, high solubility active ingredient which is an antidiabetic drug selected from the group consisting of metformin hydrochloride, phenformin and buformin and one or more hydrophobic release controlling agent wherein the weight ratio of high dose, high solubility active ingredient and hydrophobic release controlling agent is in the range of 100:2.5 to 100:30 and ~~the low dose active ingredient is an antidiabetic drug selected from the group consisting of glibenclamide (glyburide), glipizide, gliclazide, glimepiride, tolazamide, tolbutamide, clorpropamide, gliquidone, nateglinide,~~

~~mitiglinide, glyburide, glisoxepid, glibernuride, phenbutamide, tolcyclamide, repaglinide, troglitazone, ciglitazone, rosiglitazone, pioglitazone, englitazone, acarbose, voglibase, emiglitate, miglitol, farglitazar, (S)-2-ethoxy-3-[4-(2-(4-methanesulfonyloxyphenyl)ethoxy)phenyl]propanoic acid, 3-[4-(2-4-tert-butoxycarbonyl aminophenyl)ethoxy]phenyl]- (S)-2-ethoxypropanoic acid and pharmaceutically acceptable salts thereof and the high dose high solubility active ingredient is an antidiabetic drug selected from the group consisting of metformin hydrochloride, phenformin and buformin.~~

b) a coating of one or more hydrophobic release controlling agents on said micro matrix particles, wherein the weight ratio of micromatrix particles and hydrophobic release controlling agent is in the range of 100:2.5 to 100:30.